EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Kathryn Piffat on 10/29/2010. Claims 15, 16 and 42 are allowed.

Please amend the claims as they appear below:

Replace Claim 15 as follows:

Claim 15. A method of screening for a potential prophylactic/therapeutic agent for respiratory diseases, which comprises:

(i) culturing a cell expressing a protein in the presence and absence of a test compound and measuring cholesterol hydroxylation activity of the protein, wherein the protein comprises (a) the amino acid sequence of SEQ ID NO: 2 or (b) an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 2 and having cholesterol hydroxylation activity, or a salt thereof;

(ii) comparing the measured cholesterol hydroxylation activity of the protein in the presence of the test compound with the measured activity of the protein in the absence of the test compound;

(iii) selecting the test compound which decreases cholesterol hydroxylation activity of the protein by at least 20%;

(iv) measuring and comparing the production of inflammatory cytokines in the presence and absence of the test compound selected in step (iii); and

(v) selecting the test compound which decreases the production of inflammatory cytokines as the prophylactic/therapeutic agent for respiratory diseases.

Claim 16. Replace "represented by" with "of".

REASONS FOR ALLOWANCE

The following is an Examiner's statement of reasons for allowance. While Russell et al. (Cholesterol 25-Hydroxylase, WO 2000/23596, published on 04/27/2000, see IDS) specifically teaches a method of screening for an agent that modulates the interaction of human cholesterol 25-hydroxylase polypeptide as set forth in SEQ ID NO: 2 (which is identical to Applicant's SEQ ID NO: 2, see below sequence alignment from SCORE 20091211_121822_us-10-594-266-2.rag), to a binding target, said method comprising the steps of: incubating a mixture comprising said polypeptide, a binding target of said polypeptide, and a candidate agent; detecting the binding affinity of said polypeptide to said binding target to determine an agent-biased affinity, wherein a difference between the agent-biased affinity and the reference affinity indicates that said agent modulates the binding of said polypeptide to said binding target, the Examiner

has found no teaching or suggestion in the prior art directed to a method of screening for a potential prophylactic/therapeutic agent for *respiratory diseases*, which comprises: (i) culturing a cell expressing a protein in the presence and absence of a test compound and measuring cholesterol hydroxylation activity of the protein, wherein the protein comprises (a) the amino acid sequence of SEQ ID NO: 2 or (b) an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 2 and having cholesterol hydroxylation activity, or a salt thereof; (ii) comparing the measured cholesterol hydroxylation activity of the protein in the presence of the test compound with the measured activity of the protein in the absence of the test compound; (iii) selecting the test compound which decreases cholesterol hydroxylation activity of the protein by at least 20%; *(iv) measuring and comparing the production of inflammatory cytokines in the presence and absence of the test compound selected in step (iii); and (v) selecting the test compound which decreases the production of inflammatory cytokines as the prophylactic/therapeutic agent for respiratory diseases* (italicized for added emphasis). Therefore, the claimed invention is novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached between 9:00 to 5:30 on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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